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a suction lumen communicating from the proximal end of the catheter body to the distal end of the catheter body; and
a plurality of suction ports located on the distal end of the catheter communicating from the suction lumen to the exterior of the catheter body, wherein at least one of the plurality of suction ports is disposed between each pair of heating elements, whereby suction applied to the vessel through the plurality of suction ports will draw the tissue of the vessel near each of the plurality of valves toward each pair of heating elements; and
a vacuum source operably connected to the suction lumen.

Remarks

Claims 1-5, 9 and 10 remain pending in the application.

On January 14, 2003, the Examiner issued an Advisory Action which stated that the amendments presented in the December 23, 2003 response to the Office Action of October 24, 2002 would not be entered. This response addresses the outstanding Office Action of October 24, 2002.

An RCE is included with this Office Action response. Applicant therefore requests that the amendments be considered and that the claims be allowed. Applicant has amended independent claims 1, 9 and 10 to include a vacuum source operably connected to the suction lumen. The vacuum source is not shown in the art cited by the Office Action.

The Office Action rejected claims 1 through 5 as anticipated by Swartz et al., Process and Device for the Treatment of Atrial Arrhythmia, U.S. Patent 5,938,660 (Aug. 17, 1999) under the assertion that Swartz discloses a device having a catheter body, first and second balloons, a heating element, a suction lumen

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having a suction port, and different sources of energy used for catheter ablation such as direct current and RF energy.

Swartz does not disclose a vacuum source and therefore, contrary to the assertion of the Office Action, does not show a suction port or all the limitations of the claims. Thus, Swartz does not anticipate claims 1-5, 9 or 10. Swartz also does not suggest a vacuum source since Swartz does not use suction to draw tissue near a valve toward his RF electrode. Instead, Swartz introduces a conductive media into the space between his two balloons and then applies RF energy to the conductive media to ablate a heart blood vessel. Indeed, the Swartz device will not repair valves since Swartz does not attempt shrink the lumen he seeks to ablate, and Swartz provides no mechanism or feature for doing so. On the other hand, Applicant's claims include a vacuum source that, when in use with the device, will cause tissue to come in contact with the electrodes. Swartz shows no such limitation as he avoids placing tissue in contact with his electrodes.

The Office Action rejected claims 1-5 and 9-10 as anticipated by Ramsey, III, Esophageal Catheters and Method of Use, U.S. Patent 6,148,222 (Nov. 14, 2000) under the assertion that Ramsey discloses a device having a catheter body, first and second balloons located at the distal end of the catheter, a first and second heating element and wires. The Office Action also asserted that Ramsey shows a plurality of balloons, a plurality of suction lumens and a plurality of heating elements and wires.

Ramsey does not disclose a vacuum source and thus Ramsey does not disclose all of the limitations of the claims. In addition, Ramsey does not render the claims obvious since Ramsey does not use suction to draw tissue toward his electrodes. Instead, Ramsey introduces a conductive media into the space between his balloons and then applies electrical energy to defibrillate the heart. Indeed, Ramsey specifically teaches away from the claims since he

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specifically seeks to avoid ablating the esophagus; thus, he cannot show a suction lumen as proposed by the Office Action. Ramsey would certainly never add any lumen to a device that would result in drawing the tissue of the esophagus towards his electrode, because his device is not intended to thermally damage any part of the esophagus. Doing so would be contradictory to the several features he mentions which are intended to protect the esophagus. Thus, Ramsey does not suggest claims 1-5, 9 and 10.

In addition, with respect to claim 4, Ramsey does not disclose a heating element. Ramsey does show electrodes for propagating a current into the body, but he specifically avoids heating of any kind. Accordingly, the Ramsey electrodes do not comprise heating elements. Thus Ramsey does not anticipate claim 4.

The Office Action rejected claims 4 and 5 as obvious over Swartz in view of Laufer et al., Method of Treating a Bronchial Tube with a Bronchial Stenter Having Diametrically Adjustable Electrodes, U.S. Patent 6,283,989 (Sep. 24, 2001) under the assertion that Swartz substantially discloses the claimed invention, that it is inherent that the electrode is connected through wires to the RF energy source, that Laufer teaches electrodes for delivering heat from an RF energy supply and that it would have been obvious to modify the electrode as taught by Laufer.

Neither reference shows a vacuum source, so the proposed combination does not result in the claimed invention. Moreover, there is no suggestion to add a vacuum source to either Swartz or Laufer. Accordingly, claims 1-5, 9 and 10 are not obvious in view of Swartz and Laufer. Regarding claim 4, the rejection ignores the limitation of the resistive heating element. Thus claim 4 is not obvious over Swartz in view of Laufer.

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In addition, the Office Action does not provide a motivation to combine the references and thus has failed to create a prima facie obviousness rejection. Indeed, there can be no motivation to combine the references since neither reference shows all of the limitations of the claims; thus, the claims are not obvious over Swartz in view of Laufer.

Conclusion

This response has addressed all of the Examiner's grounds for rejection. The rejections based on prior art have been traversed. Reconsideration of the rejections and allowance of the claims is requested.

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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

In re Application of:

Mollenauer, et al.

Serial No.: 09/598,852

Filed: June 20, 2000

For: Devices and Methods for
Repair of Valves in the Human
Body

Art Unit: 3763

Examiner: Thanh, L.

ATTACHMENT OF CLAIMS AND AMENDED SPECIFICATION PARAGRAPHS

The claims, including those amended by the Response submitted herewith on March 14, 2003, are as follows:

1. (amended) A device for treating an incompetent anatomical valve or sphincter within the body of a patient, wherein said valve or sphincter controls flow of fluid through a vessel of the body and is supported by tissue of the vessel near the valve, said device comprising:

a catheter body having a distal end and a proximal end, said distal end being adapted for insertion into the body;

a first balloon located at the distal end of the catheter, said first balloon being inflatable to a diameter greater than the catheter body distal end, and a first inflation lumen communicating from the proximal end of the catheter body to the distal end of the catheter body;

a heating element mounted on the distal end of the catheter, proximal to the first balloon;

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a suction lumen communicating from the proximal end of the catheter body to the distal end of the catheter body, and a suction port located on the distal end of the catheter communicating from suction lumen to the exterior of the catheter body, said suction port being located proximal the heating element; whereby suction applied to the vessel through the suction port will draw the tissue of the vessel near the valve toward the heating element; and

a vacuum source operably connected to the suction lumen.

2. (unchanged) The device of claim 1 further comprising:

a second balloon located at the distal end of the catheter, proximal to the first balloon, the heating element and suction port, said second balloon being inflatable to a diameter greater than the catheter body distal end.

3. (unchanged) The device of claim 2 further comprising:

a second inflation lumen communicating from the proximal end of the catheter body to the second balloon on the distal end of the catheter body.

4. (unchanged) The device of claim 1 further comprising:

a pair of wires running from the heating element to the proximal end of the catheter, said wires adapted to electrically connect the heating element to direct current power supply; and

wherein the heating element is a resistive heating element.

5. (unchanged) The device of claim 1 further comprising:

a wire running from the heating element to the proximal end of the catheter, said wire adapted to electrically connect the heating element to a radiofrequency power supply; and

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wherein the heating element is a radiofrequency electrode adapted for transmission of radiofrequency energy into the tissue of the vessel.

9. (amended) A device for treating an incompetent anatomical valve or sphincter within the body of a patient, wherein said valve or sphincter controls flow of fluid through a vessel of the body and is supported by tissue of the vessel near the valve, said device comprising:

- a catheter body having a distal end and a proximal end, said distal end being adapted for insertion into the body;

- a first balloon located at the distal end of the catheter, said first balloon being inflatable to a diameter greater than the catheter body distal end, and a first inflation lumen communicating from the proximal end of the catheter body to the distal end of the catheter body, wherein the first inflation lumen is in fluid communication with the first balloon;

- a first heating element mounted on the distal end of the catheter, proximal to the first balloon;

- a second balloon located at the distal end of the catheter, said second balloon being inflatable to a diameter greater than the catheter body distal end, said second balloon proximal to the first balloon and proximal to the first heating element, and a second inflation lumen communicating from the proximal end of the catheter body to the distal end of the catheter body, wherein the second inflation lumen is in fluid communication with the second balloon;

- a second heating element mounted on the distal end of the catheter, distal to the second balloon and proximal to the first heating element;

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a suction lumen communicating from the proximal end of the catheter body to the distal end of the catheter body, and at least one suction port located on the distal end of the catheter communicating from the suction lumen to the exterior of the catheter body, said at least one suction port being located proximal to the first heating element and distal to the second heating element; whereby suction applied to the vessel through the at least one suction port will draw the tissue of the vessel near the valve toward the first and second heating elements; and

a vacuum source operably connected to the suction lumen.

10. (amended) A device for treating a plurality of incompetent anatomical valves or sphincters within the body of a patient, wherein said plurality of valves or sphincters control flow of fluid through a vessel of the body and are supported by tissue of the vessel near the plurality of valves, said device comprising:

a catheter body having a distal end and a proximal end, said distal end being adapted for insertion into the body;

a first balloon located at the distal end of the catheter, said first balloon being inflatable to a diameter greater than the catheter body distal end, and a first inflation lumen communicating from the proximal end of the catheter body to the distal end of the catheter body, wherein the first inflation lumen is in fluid communication with the first balloon;

a second balloon located at the distal end of the catheter, said second balloon being inflatable to a diameter greater than the catheter body distal end, said second balloon proximal to the first balloon, and a second inflation lumen communicating from the proximal end of the catheter body to the distal end of the catheter body, wherein the second

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inflation lumen is in fluid communication with the second balloon;

a plurality of heating elements mounted on the distal end of the catheter body, wherein each of the plurality of heating elements are disposed in series along the length of the catheter body, wherein two succeeding heating elements comprise a pair of heating elements, and wherein the pair of heating elements are further disposed on the catheter body such that a section of catheter body separates each pair of heating elements; and

a suction lumen communicating from the proximal end of the catheter body to the distal end of the catheter body; and

a plurality of suction ports located on the distal end of the catheter communicating from the suction lumen to the exterior of the catheter body, wherein at least one of the plurality of suction ports is disposed between each pair of heating elements, whereby suction applied to the vessel through the plurality of suction ports will draw the tissue of the vessel near each of the plurality of valves toward each pair of heating elements; and

a vacuum source operably connected to the suction lumen.

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